

connection path) between the audiometer earphone and the patient's ear.

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in subpart E of part 807.

[51 FR 40389, Nov. 9, 1986; 52 FR 18495, May 15, 1987, as amended at 52 FR 32111, Aug. 25, 1987]

§ 874.1120 Electronic noise generator for audiometric testing.

(a) *Identification.* An electronic noise generator for audiometric testing is a device that consists of a swept frequency generator, an amplifier, and an earphone. It is intended to introduce a masking noise into the non-test ear during an audiometric evaluation. The device minimizes the non-test ear's sensing of test tones and signals being generated for the ear being tested.

(b) *Classification.* Class II.

§ 874.1325 Electroglottograph.

(a) *Identification.* An electroglottograph is an AC-powered device that employs a pair of electrodes that are placed in contact with the skin on both sides of the larynx and held in place by a collar. It is intended to measure the electrical impedance of the larynx to aid in assessing the degree of closure of the vocal cords, confirm laryngeal diagnosis, aid behavioral treatment of voice disorders, and aid research concerning the laryngeal mechanism.

(b) *Classification.* Class II.

§ 874.1500 Gustometer.

(a) *Identification.* A gustometer is a battery-powered device that consists of two electrodes that are intended to be placed on both sides of the tongue at different taste centers and that provides a galvanic stimulus resulting in taste sensation. It is used for assessing the sense of taste.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180 with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

§ 874.1800 Air or water caloric stimulator.

(a) *Identification.* An air or water caloric stimulator is a device that delivers a stream of air or water to the ear canal at controlled rates of flow and temperature and that is intended for vestibular function testing of a patient's body balance system. The vestibular stimulation of the semicircular canals produce involuntary eye movements that are measured and recorded by a nystagmograph.

(b) *Classification.* Class I.

[55 FR 48440, Nov. 20, 1990]

§ 874.1820 Surgical nerve stimulator/locator.

(a) *Identification.* A surgical nerve stimulator/locator is a device that is intended to provide electrical stimulation to the body to locate and identify nerves and to test their excitability.

(b) *Classification.* Class II.

§ 874.1925 Toynbee diagnostic tube.

(a) *Identification.* The toynbee diagnostic tube is a listening device intended to determine the degree of openness of the eustachian tube.

(b) *Classification.* Class I.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 874.3300 Hearing Aid.

(a) *Identification.* A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (§ 874.3320), master hearing aid (§ 874.3330), and tinnitus masker (§ 874.3400).

(b) *Classification.* (1) Class I for the air-conduction hearing aid. (2) Class II for the bone-conduction hearing aid.

§ 874.3310 Hearing aid calibrator and analysis system.

(a) *Identification.* A hearing aid calibrator and analysis system is an electronic reference device intended to calibrate and assess the electroacoustic frequency and sound